

Listing of the Claims

1. (Currently Amended) A liquid pharmaceutical formulation consisting essentially of human interferon- β as an active ingredient in a concentration of ~~up to 25~~ less than 12 $\times 10^6$ U/ml and a buffer which buffers in a pH range of 5 to 8, with the proviso that the formulation does not contain human serum albumin, and, optionally, at least one physiologically acceptable preservative, wherein after storage for 3 months at 25°C, stability of in vitro biological activity of the formulation is at least 80% of an initial biological activity, wherein said biological activity comprises inhibition of a cytopathic effect of a virus.

2. (Previously presented) The liquid formulation according to Claim 1, wherein the buffer buffers in a pH range of 6 to 7.2.

3. (Currently amended) A liquid formulation comprising a glycosylated human interferon- β as an active ingredient, a buffer ~~for buffering which buffers~~ in a pH range of 5 to 8, and methionine, with the proviso that the formulation does not contain human serum albumin, and wherein after storage for 3 months at 25°C, stability of an in vitro biological activity of the formulation is at least 80% of an initial biological activity, wherein said biological activity comprises inhibition of a cytopathic effect of a virus.

4. (Previously presented) The formulation according to Claim 1, wherein the interferon- β is a glycosylated interferon- β .

5. (Previously presented) The formulation according to Claim 1, wherein the interferon- β is recombinantly produced in CHO cells.

6. (Previously presented) The formulation according to Claim 1, wherein the buffer is

Appl. No. 09/508,510
Amdt. Dated March 23, 2004
Reply to Final Office Action of June 26, 2003

in a concentration of 10 mmol/l to 1 mol/l.

7. (Previously presented) The formulation according to Claim 1, wherein the buffer is selected from the group consisting of a phosphate, a citrate and an acetate buffer, and a combination thereof.

8. (Previously presented) The formulation according to Claim 7, wherein the buffer comprises a phosphate/citrate buffer.

9. (Previously presented) The formulation according to Claim 3, wherein the pH is between 6 and 7.2.

10. Canceled.

11. (Previously presented) The formulation according to Claim 3, wherein the active ingredient is free from human or animal polypeptides.

12. (Previously presented) The formulation according to Claim 3, wherein the formula is free from surfactants.

13. (Previously presented) The formulation according to Claim 1, wherein after storage of the formulation for 6 months at 25°C, the formulation is chemically stable.

14. (Previously presented) The formulation according to Claim 1, wherein after storage of the formulation for 6 months at 25°C, the formulation is physically stable.

15-16. Canceled.

Appl. No. 09/508,510
Amdt. Dated March 23, 2004
Reply to Final Office Action of June 26, 2003

17. (Previously presented) The formulation according to Claim 3, wherein the methionine is present in a concentration of 0.1 to 4 mmol/l.

18. (Previously presented) The formulation according to Claim 3, further comprising an ingredient for adjusting tonicity.

19. (Previously presented) The formulation according to Claim 3, comprising a thickener for increasing viscosity.

20. (Previously presented) The formulation according to Claim 3, further containing at least one physiologically acceptable preservative.

21. (Previously presented) A pharmaceutical composition comprising a liquid formulation according to Claim 1, and a pharmaceutically acceptable carrier.

22. (Previously presented) The pharmaceutical composition according to Claim 21 in a form suitable for oral, parenteral or ophthalmological administration.

23. (Previously presented) The pharmaceutical composition according to Claim 21, wherein the composition is in the form of a unit containing 1 to 25×10^6 IU of interferon- β .

24. Canceled.

25. (Currently amended) A process for stabilizing a liquid formulation comprising human interferon- β as an active ingredient and a buffer for buffering in a pH range of 5 to 8, said process comprising adding a stabilizing amount of methionine to the formulation, with the further proviso that human serum albumin is not present in the formulation.

Appl. No. 09/508,510
Amdt. Dated March 23, 2004
Reply to Final Office Action of June 26, 2003

26. (Previously presented) The process according to Claim 25, wherein the stabilizing comprises increasing at least one of the long-term stability of the in vitro biological activity, the chemical stability and the physical stability of the formulation.

27. (Previously presented) A pharmaceutical composition comprising a liquid formulation according to Claim 3, and a pharmaceutically acceptable carrier.

28. (Previously presented) The pharmaceutical composition according to Claim 27 in a form suitable for oral, parenteral or ophthalmological administration.

29. (Previously presented) The pharmaceutical composition according to Claim 27, wherein the composition is in the form of a unit containing 1 to 25×10^6 IU of interferon- β .

30-31. (Canceled)

32. (New) A liquid formulation consisting of human interferon- β , 70 mmol/L sodium citrate, 50 mmol/L sodium phosphate, and 2 mmol/L methionine, having a pH in a range of about 6.2 to about 6.8.

33. (New) The liquid formulation of claim 32, wherein the formulation has a pH of about 6.5.